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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,334	07/10/2003	Michael R. Hayden	760050-91	5209

7590 12/29/2005

CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI,
STEWART & OLSTEIN
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,334	HAYDEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1-56 are pending in the application.

[3] Receipt of an information disclosure statement (IDS), filed on 7/10/2003, is acknowledged. It is noted that this IDS incorrectly lists the application number as 09/526,193. Also, it is noted that none of the cited references has been considered by the examiner in the instant application. However, certain references of this IDS already have been initialed and signed. Further, one of the references is cited on Form PTO-892 and not on Form PTO-1449. Appropriate correction is required.

[4] Applicants' amendment to the specification, filed on 11/13/2003, is acknowledged.

[5] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 121 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 121 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional

parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Election/Restrictions

[6] Claims 1 and 18-23 link(s) inventions I-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 18-23.

[7] Claims 24 and 41-45 link(s) inventions V-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 24 and 41-45.

[8] Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In*

re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

[9] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-5, 46-48, drawn to a method for treating a mammal having a disorder of cholesterol metabolism by administering a compound that modulates ABCA1 *in vitro* lipid transport across a membrane, classified in class 514, subclass 789.

II. Claims 6-8, 46-48, drawn to a method for treating a mammal having a disorder of cholesterol metabolism by administering a compound that modulates ABCA1 *in vitro* ion transport across a membrane, classified in class 514, subclass 789.

III. Claims 9-11, 46-48, drawn to a method for treating a mammal having a disorder of cholesterol metabolism by administering a compound that modulates ABCA1 *in vitro* interleukin-1 transport across a membrane, classified in class 514, subclass 789.

IV. Claims 12-17, 46-48, drawn to a method for treating a mammal having a disorder of cholesterol metabolism by administering a compound that modulates ABCA1 ATP binding or hydrolysis, classified in class 514, subclass 789.

V. Claims 25-28, 49, drawn to a method for treating a mammal having or at risk of developing a cardiovascular disease by administering a compound

that modulates ABCA1 *in vitro* lipid transport across a membrane, classified in class 514, subclass 789.

VI. Claims 29-31, 49, drawn to a method for treating a mammal having or at risk of developing a cardiovascular disease by administering a compound that modulates ABCA1 *in vitro* ion transport across a membrane, classified in class 514, subclass 789.

VII. Claims 32-34, 49, drawn to a method for treating a mammal having or at risk of developing a cardiovascular disease by administering a compound that modulates ABCA1 *in vitro* interleukin-1 transport across a membrane, classified in class 514, subclass 789.

VIII. Claims 35-40, 49, drawn to a method for treating a mammal having or at risk of developing a cardiovascular disease by administering a compound that modulates ABCA1 ATP binding or hydrolysis, classified in class 514, subclass 789.

IX. Claims 50, drawn to a method of preventing cardiovascular disease in a human by administering an expression vector comprising an ABCA1 polynucleotide, classified in class 514, subclass 44.

X. Claim 51, drawn to a method for preventing or ameliorating the effects of a disease-causing mutation in an *ABCA1* gene in a human by administering an expression vector comprising an ABCA1 polynucleotide, classified in class 514, subclass 44.

XI. Claims 52-56, drawn to a method of treating or preventing cardiovascular disease by administering a compound that that mimics wild-type ABCA1 activity, classified in class 514, subclass 789.

[10] If applicant elects the invention of Group XI, applicant is further required under 35 U.S.C. 121 to elect one of the following compounds for examination on the merits:

a. Protein Kinase A

b. Protein Kinase C

c. Vanadate

d. Okadaic acid

e. IBMX1

f. Fibrates

g. Gamma-estradiol

h. Arachidonic acid derivatives

i. WY-14,643

j. LTB4

k. 8(s)HETE

l. Thiozolidinedione antidiabetic drugs

m. 9-HODE

n. 13-HODE

o. Nicotinic acid

p. HMG CoA reductase inhibitors

q. Compounds that increase PPAR-mediated ABCA1 expression

[11] The inventions are distinct, each from the other because:

[12] The compounds of Groups a to q are structurally distinct and no single compound of Groups a to q would render any of the others obvious to one of ordinary skill in the art.

[13] The methods of Groups I-XI are unrelated as the methods require different method steps, utilize different products, and/or yield different results.

[14] This application contains claims directed to the following patentably distinct species of the claimed invention: 1) Claim 46 recites Alzheimer's disease, Niemann-Pick disease, Huntington's disease, X-linked adrenoleukodystrophy, and cancer and 2) claims 49 and 55 recite Coronary artery disease, Cerebrovascular disease, Coronary restenosis, and Peripheral vascular disease.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 46, 49, and 55 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

[15] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, the inventions of Groups a to q and I-XI are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions listed as Groups a to q and I-XI would require a separate patent and non-patent literature search. As such, co-examination of the inventions of Groups a to q and I-XI would require a serious burden on the examiner.

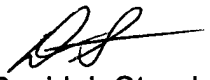
[16] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[17] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656